REMARKS

I. Status of the Claims

In the Office Action of August 24, 2006, the Examiner rejected claims 81-83, 86-92, 94-102, 105-111, and 113-118 under 35 U.S.C. § 102(b) as allegedly being anticipated by U.S. Patent No. 6,193,692 to Harris et al. ("Harris"). As an initial matter, Applicants note that Harris does not qualify as prior art under 35 U.S.C. § 102(b) since this application claims priority under 35 U.S.C. § 120 to U.S. Application 09/450,599, filed November 30, 1999. (See, e.g., the Preliminary Amendment of December 15, 2003, in this case). Therefore, since Harris was not "patented in this. . . country. . . more than one year prior to the date of the application for patent in the United States" as required by 35 U.S.C. § 102(b), Harris only qualifies as prior art under 35 U.S.C. § 102(e).

Applicants hereby amend claims 81 and 100 to more clearly define the claimed invention. The originally-filed specification, claims, abstract, and drawings fully support the subject matter of the amended claims. No new matter is introduced. The rejection of independent claims 81 and 100, and the claims dependent thereon, is traversed for the reasons discussed below.

II. The Pending Claims are Not Anticipated by Harris

The Examiner rejected claims 81-83, 86-92, 94-102, 105-111, and 113-118 as allegedly being anticipated by Harris. Under 35 U.S.C. § 102, "[a] claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." M.P.E.P. § 2131 (8th ed. 2001), p. 2100-70, quoting *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). Furthermore, "[t]he identical invention must be shown in as complete detail as is contained in the . . . claim." *See* M.P.E.P. § 2131, quoting *Richardson v. Suzuki Motor Co.*, 868 F.2d 1126, 1236, 9 U.S.P.Q.2d 1913, 1920 (Fed. Cir. 1989). Finally, "[t]he elements must be arranged as required by the claim." M.P.E.P. § 2131.

A. Harris Fails to Teach Recitations of Claim 81

Claim 81 includes the recitation "wherein the first assembly and the second assembly seal together and are separable, and such that body fluid cannot pass through the needle when the first and second assemblies are sealed together." In addition, claim 81, as amended, recites that "fluid cannot pass through the entry needle when the hub is in the second position and the entry needle is substantially unimpeded by tissue." In rejecting claim 81, the Examiner points to the embodiment of FIG. 10 and item 84 of Harris as disclosing a feature preventing fluid flow. (See August 24, 2006, Office Action, Page 3).

More particularly, on page 3 of the August 24, 2006, Office Action, the Examiner points to column 5, lines 6-10 and 48 of Harris and asserts that:

> The device operates to seal by a simple half twist or a rotation of approximately one hundred and eighty degrees of the stylet subassembly 30. Clearly, in the embodiment of figure 10, when this half twist occurs, *plug* 84 is rotated 180 degrees, resulting in a prevent of any body fluid going into the needle. Note that in column 5, lines 62-64, Harris clearly states that the flow path is through the gap between the inner bore and the solid projection. Other valves are described in the following lines. In addition, valve 36 would prevent fluid flow. The examiner takes the position that "plug" is an action word that further defines that this piece plugs the distal end of the cannula.

Applicants dispute this interpretation of Harris for the following reasons.

Harris discloses a surgical instrument, the express purpose of which is "to inject gas into a body cavity to facilitate endoscopic surgery." (See, Harris at column 1, lines 9-10). The main components of the system in Harris comprise an outer sheath member 12, a stylet subassembly 30, and a high flow adapter subassembly 52. As set forth in column 3, lines 41-56, Harris discloses that:

> Both the stylet subassembly 30 and the high flow adaptor subassembly 52 are detachable from the outer sheath member 12. The stylet subassembly 30 is attached to the outer sheath member 12 so that the initial incision into the body cavity and **the initial injection of gas into the body cavity** can be carried out in the same manner as with the prior art verres needle 2. However, **after a small amount of gas has been injected into the body cavity to insure that no internal organs are in contact with the sharp cutting edge 15 on the distal end 16 of the outer sheath 12, the stylet subassembly 30 is removed from the outer sheath member 12.** The high flow adaptor subassembly 52 is then attached to the outer sheath member 12 so that higher pressure gas can be injected into the body cavity at a higher rate. Therefore the entire insufflation procedure can be completed in less time.

(Emphasis added). Accordingly, one required feature in the device of Harris is the capability of providing fluid flow through the stylet subassembly 30 to perform an initial injection of gas therethrough.

The following passage of column 4, lines 23-31 of Harris further describes the required feature of fluid flow through subassembly 30.

> The inner projection 32 on stylet subassembly 30 is a hollow tube with an opening adjacent the exposed end. This hollow tube 32 fits within the outer sheath 12. The inner diameter of the hollow tube or inner projection 32 is less than the inner diameter of the tubular outer sheath 12. **Therefore, the flow rate through the hollow tube 32** is less than the rate of flow that could be achieved through the outer sheath 12 alone.

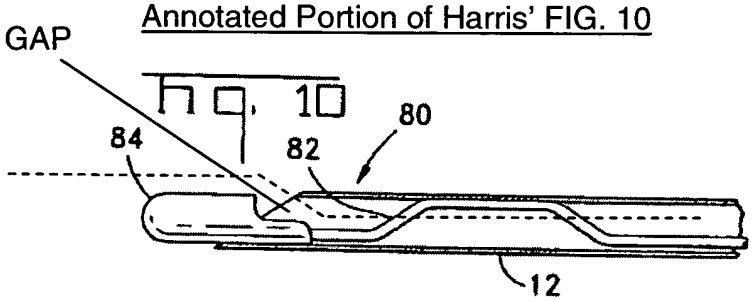
(Emphasis added).

Accordingly, the Harris device cannot meet the recitations of claim 81 since Harris requires that gas or fluid flows through outer sheath member 12 and stylet subassembly 32 for the purpose of insufflating a body cavity. The Harris device provides for fluid flow therethrough when stylet subassembly 32 and sheath 12 are connected. In addition, the Harris device provides for fluid flow through the needle when the needle is unimpeded by tissue.

In the embodiment shown in FIG. 10 of Harris, the inner projection 32 of the stylet subassembly is replaced with an inner projection 82 and a plug section 84, which extends beyond the outer sheath member 12. The passages referred to by the Examiner, however, expressly disclose that "[t]he **flow path for this configuration** is through the gap between the inner bore 20 [of sheath member 12] and the solid projection 82." (Harris at column 5, lines 62-64.) (Emphasis added.) While the

presence of item 82 in tubular sheath 12 may partially restrict the flow path therethrough (see Harris at column 5, lines 64-67), just as inner projection 32 may (see Harris at column 4, lines 29-31), nothing in the embodiment of FIG. 10 prevents fluid from passing therethrough when the needle is unimpeded by tissue. To the contrary, lines 62-64 of column 5 in Harris expressly disclose that fluid **does** flow through sheath 12. As explained above, providing the capability for fluid flow therethrough is the underlying purpose for the devices of Harris. Accordingly, as seen in the annotated portion of Harris's FIG. 10 (reproduced below), fluid flow is depicted by the added dashed path.[1]

Annotated Portion of Harris' FIG. 10



The Examiner argues that "in the embodiment of figure 10, *plug* 84 is rotated 180 degrees, resulting in a prevent of any body fluid going into the needle." (August 24, 2006, Office Action, pages 3-4). This is baseless speculation unsupported by the disclosure of Harris. The disclosure of Harris omits any discussion explaining how item 84 would serve to prevent fluid flow through sheath 12.

For example, in FIG. 10 of Harris, it is unclear whether the inner projection 82 is depicted before or after the mating of the male and female members described in column 5, lines 5-12 of Harris. As such, it is unclear whether the inner projection 82 is

[1] Please note that the dashed flowpath in annotated FIG. 10 above is included by Applicants for purposes of explanation and is not part of the drawings of Harris.

illustrated relative to the sheath 12 before or after the described one hundred and eighty degree rotation. As will be described, however, one configuration (after rotation) results in an arrangement incapable of meeting the recitations of claim 81 and another configuration (before rotation) results in an inoperable device.

First, if the relative positions illustrated in FIG. 10 depict the inner projection 82 in a final mating position (i.e., after a 180 degree rotation), then item 84 is shown in its default resting position with spring 48 biasing item 84 into the distal extended position depicted. In this position, item 84 is unimpeded by tissue and therefore serves to provide "a gap between the inner bore 20 [of sheath member 12] and the solid projection 82." (Harris at column 5, lines 62-64.) This gap provides the necessary area creating the dashed flowpath (see annotated version of FIG. 10 above), thereby allowing the injection of gas therethrough, which is a required feature of Harris.

When a user operates the needle of FIG. 10 to create an incision, the force of tissue against the distal end of the needle partially retracts item 84 into sheath 12, against the force of spring 48, until the cutting edge of sheath 12 punctures tissue. Once the wall of a cavity is pierced, the distal end of the needle will no longer be impeded by tissue and item 84 then returns to its extended default resting position, depicted in FIG. 10. At this stage, the required initial fluid flow as described in column 3, lines 41-56 of Harris is then commenced. Accordingly, fluid flow through the entry needle when item 84 is unimpeded by tissue is a required and expressly disclosed feature of Harris.

Harris therefore cannot meet the recitations of claim 81 reciting that "fluid cannot pass through the entry needle when the hub is in the second position and the entry

needle is substantially unimpeded by tissue." Therefore, this potential configuration of Harris cannot anticipate claim 81.

Second, if the relative positions illustrated in FIG. 10 depict the inner projection 82 prior to achieving a final mating position, then the final configuration (i.e., after a 180 degree rotation of item 82) may result in a sealing of inner bore 20 by virtue of alignment between item 84's proximal extension and the beveled opening at the distal end of sheath 12. In other words, upon a 180 degree rotation of item 82 and item 84 relative to sheath 12, the proximal extension of item 84 may block all fluid flow between inner bore 20 and the area outside the distal end of sheath 12. Such a configuration, however, would not occur in the device of Harris since it would render the device inoperable for its intended purpose. As stated above, one required feature of Harris is the capability of providing fluid flow through the stylet subassembly 30 to perform an initial injection of gas therethrough. (See, e.g., Harris at column 3, lines 41-56). Under such a proposed configuration, fluid cannot pass through the entry needle when the entry needle is substantially unimpeded by tissue. Accordingly, no interpretation of the FIG. 10 device of Harris meets the language of claim 81.

Page 4 of the August 24, 2006 Office Action explains that the examiner considers the use of the term "plug" for item 84 as an "action" word. As such, the examiner interprets item 84 as a piece that plugs the distal end of the cannula. This is not expressly disclosed in Harris. If the Examiner is arguing that Harris anticipates the claims based on inherency as described in § 2112 of the M.P.E.P., Applicants point out that "[t]o establish inherency, the extrinsic evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that

it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient." M.P.E.P. § 2112 (8th ed. 2001), p. 2100-57, quoting *In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999)

Here, inherency has not been established since it is not necessarily the case that item 84 "plugs" the distal end of sheath 12 such that "fluid cannot pass through the entry needle when the hub is in the second position and the entry needle is substantially unimpeded by tissue," as recited by claim 81. In fact, it is most probably not the case. Consistent with the remarks above concerning FIG. 10 of Harris, a required feature of Harris is the capability for providing fluid flow. In summary, no portion of the Harris reference provides support for the contention that item 84 "plugs" the distal end of sheath 12 when the needle is unimpeded by tissue.

Finally, regarding the Examiner's argument that valve 36 would prevent fluid flow through subassembly 30, Applicants point out that the hollow tube 32 (and the subassembly 80 of FIG. 10, for that matter) includes an open distal end for permitting fluid flow. Even where valve 36 is closed, fluid can enter the internal lumen of hollow tube 32 distal of valve 36. In contrast, in the present invention recited in claim 81, fluid cannot pass through the needle when the first and second assemblies are sealed together.

For at least the reasons presented above, Harris does not teach each and every element as set forth in claim 81. Accordingly, a *prima facie* case of anticipation has not

been established and Applicants respectfully request that the rejection of claims 81-83, 86-92, and 94-99 in view of Harris be withdrawn and the claims allowed.

B. Harris Fails to Teach Recitations of Claim 100

Claim 100, as amended, recites an entry needle "wherein the first assembly and the second assembly seal together and are separable, and such that body fluid cannot pass through the *cannula* when the first and second assemblies are sealed together." In addition, claim 100 recites the requirement that "fluid cannot pass through the *cannula* when the hub is in the second position and the entry needle is substantially unimpeded by tissue." (Emphasis added).

In rejecting previous claim 100, the Examiner explains that claim 100 "differs by one word, cannula as opposed to needle, and the arguments above are applicable to this claim and dependent claims as well." (See August 24, 2006, Office Action, Page 4). In rejecting claim 81, the Examiner points to sheath 12 of Harris as corresponding to the claimed cannula. (See August 24, 2006, Office Action, Page 3).

For all the same reasons presented above in the prior section concerning claim 81, the Harris device also cannot meet the recitations of claim 100. In short, Harris requires that gas or fluid flows through outer sheath member 12 (relied upon by the Examiner as corresponding to the claimed cannula) and stylet subassembly 32 for the purpose of insufflating a body cavity. The Harris devices provide for fluid flow therethrough when stylet subassembly 32 and sheath 12 are connected. In addition, the Harris devices provide for fluid flow through the sheath member 12 when the entry needle is substantially unimpeded by tissue.

Accordingly, for at least these reasons, Harris does not teach each and every element as set forth in claim 100, a *prima facie* case of anticipation has not been established, and Applicants respectfully request that the rejection of claims 100-102, 105-111, and 113-118 in view of Harris be withdrawn and the claims allowed.

III. Conclusion

For the reasons given above, Applicants respectfully request reconsideration and allowance of pending claims 81-83, 86-92, 94-102, 105-111, and 113-118.

Please grant any extensions of time required to enter this response and charge any additional required fees to our deposit account 06-0916.

Respectfully submitted,

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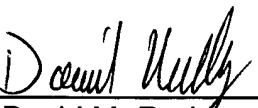
GARRETT & DUNNER, L.L.P.

Dated: November 17, 2006

By: 
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